Rational Pharmaceutical Management Plus
Antimalarial Drug Policy Implementation Review Workshop: Trip Report

Marion Lynders

September 2005

Rational Pharmaceutical Management Plus
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U.S. Agency for International Development
Strategic Objective 5

This report was made possible through support provided by the U.S. Agency for International Development, under the terms of cooperative agreement number HRN-A-00-00-00016-00. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

About RPM Plus

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

Recommended Citation

Lynders, M. 2005. *Antimalarial Drug Policy Implementation Review Workshop: Trip Report* Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

Key Words

Policy, malaria, artemisinin combination therapy

Contents

ACRONYMS

ACT	Artemisinin-based combination therapy
ACTMalaria	Asian Collaborative Training Network for Malaria
AMDP	Anti Malarial Drug Policy
CNMP	Cambodia National Malaria Program
MMFO	Managing Malaria Field Operations
RPM Plus	Rational Pharmaceutical Management Plus
WHO	World Health Organization
WPRO	WHO Western Regional Office

BACKGROUND

The Asian Collaborative Training Network for Malaria (ACTMalaria) was formed in 1996 primarily to address common malaria problems in the countries of the Mekong Region and Southeast Asia. Occupational migration which advances forest malaria transmission and the spread of multi-drug resistant *falciparum* are just two of the priority problems which the network hoped to address through joint human resource development and communication exchange. At present, the network includes national malaria programs from 10 countries in the region, namely, Bangladesh, Cambodia, PR China, Indonesia, Lao PDR, Malaysia, Burma, Philippines, Thailand and Vietnam.

Recognizing anti-malarial drug resistance as an important problem to tackle, the ACTMalaria Executive Board agreed to the development of a training course on Anti-Malarial Drug Policy Development. The course was conducted in 2000 and was co-hosted by National Malaria Control Programs of Vietnam and China. The course took into consideration the issues related to the spread of drug resistance, patient non-compliance and consumer pressure, use of anti-malarial drugs by non-qualified practitioners, and the cost-effectiveness of introducing new but more expensive anti-malarial drugs. Since then, most of the ACTMalaria member countries have revised national anti-malarial drug policies and have introduced or considered the use of combination therapy. Much of these advancements have been made possible through the Global Fund support.

Since 2002, RPM Plus has been an ACTMalaria Partner and has participated in ACTMalaria annual meetings. RPM Plus has shared with the group the methodology and findings from malaria drug use practice surveys conducted in Cambodia and Thailand (2002, 2003). Discussion has been ongoing on how to incorporate this methodology into existing training offerings. Last year, for the first time, RPM Plus participated in the Malaria Management for Field Operations (MMFO) course to present a module on drug management in malaria.

Based on the positive response of participants in the MMFO course, ACTMalaria requested RPM Plus to participate in revising the curriculum and also to design and present a training session on the pharmaceutical management aspects of implementation of ACT policy for the Anti-Malarial Drug Policy Development training course. The document, *Changing Malarial Treatment Policy to Artemisinin-Based Combination: An Implementation Guide* was used to help guide participants on the whole range of drug management related actions that need to be taken when implementing the change. This guide was developed by the RPM Plus Program in collaboration with the Roll Back Malaria Partnership and the Global Funds to Fight AIDS, Tuberculosis and Malaria with support from USAID.

Purpose of Trip

Marion Lynders from RPM Plus traveled to Wuxi city, China, from September 12-22, 2005, to present several training sessions and facilitate small group discussions on drug management

related aspects of changing malaria treatment policy to ACT at the ACTMalaria Drug Policy Development Course.

Scope of Work

- Facilitate presentations at the Drug Policy Development course by country representatives of their anti-malarial drug policy and drug resistance profiles
- Conduct training sessions on the subject of changing malarial treatment policy to artemisinin-based combination therapy (ACT), including: introduction to malaria pharmaceutical management; recognizing the operational and technical issues that need to be considered in the public and private sectors when implementing policy change; and identifying the types of technical assistance and resources that are necessary to make the change successful
- Present case studies, and facilitate discussion among country teams
- Facilitate discussions, leading to development of participant action plans

ACTIVITIES

Each of the activities listed in the scope of work was designed to be participatory and to encourage attendees to share country-level experience with colleagues from other countries from ACTMalaria member countries. Participants engaged in exercises that were designed to help them critically examine where their respective countries are in relation to the drug policy cycle, and identify challenges and strategies to address those challenges within the context of their own country. The learning objectives of the workshop can be seen in Annex 1.

Attendance during first few days of the course was low because an unexpected typhoon. Prevailing weather conditions caused several flight delays and consequently some participants arrived several days after the course began. However, by the end of the first week, twenty three participants, mostly malaria program technical staff and seven program directors from eleven countries were in attendance. None of the program directors attended the work shop during the second week leaving sixteen remaining technical staff. Representatives from the ACTMalaria partner organizations, Malaria Consortium, United States Pharamacopeia (USP), World Health Organization Western Pacific Regional Office (WPRO) and Management Sciences for Health (MSH) RPM Plus Program functioned as faculty and facilitators. Participants received copies of all presentations as well as numerous articles relating to malaria drug policy issues.

The original curriculum design and content of this course was modified to accommodate participants request for a shorter program. To facilitate a shorter time frame, presenters from ACTMalaria, WPRO, USP, RPM Plus, CDC, Malarial Consortium and the National Institute of Parasitic Diseases, China CDC, decided to present the course content to a combined group of program managers and technical staff. Marion Lynders played a role in shaping the curriculum for this particular course and participated as lecturer and facilitator for group work sessions.

The presentations from RPM Plus can be seen in Annexes 2, 3 and 4 and the case study used for the group work is in Annex 5. Annex 6 includes the Facilitator's Guide.

Initially, team members from each country presented their current antimalarial drug policy and drug resistance profile. Following RPM Plus lecture, "Changing Malaria Treatment Policy to ACT: Guide to Implementation", and as a means of learning how to utilize the guide, participants were requested to select one or more components of the implementation guide and utilizing the accompanying checklist, develop or refine the ACT policy.

Throughout the work shop, select exercises gave team members from each country the opportunity to:

1. **Identify gaps specific to the participants' home country malaria program**

Representatives from each of the ten participating countries presented their country's current antimalarial drug policy plan and drug resistance profile. Identified gaps or issues common to most countries included 1) widespread existence of counterfeit and substandard medicines, 2) lack of quality assurance programs, 3) unregulated private sector, 4) monotherapy with

artesunate, 5) difficulty in reaching marginalized communities, 6) quantification issues and 7) distribution issues.

2. **Describe the types of data that are needed to inform the development and implementation of rational malaria treatment policy**

Since most of the course participants have limited technical roles in their respective malaria programs, they had only partial understanding and knowledge about program policy. Consequently, participants struggled to identify the types of data needed to fully inform the development of a new or revision of an existing malaria treatment policy. Course facilitators worked with individual country teams to help identify the required data and information sources needed to inform the successful implementation of a rational malaria treatment policy.

3. **List potential stakeholders in the policy process and delineate their possible roles in policy development or implementation**

The process of changing an antimalarial treatment policy requires participation of others beyond that of malaria program staff and managers. Course facilitators worked with individual country teams to help identify potential stakeholders ranging from departments within the MOH, to manufacturers and private providers. A demonstration of how to use the guide as a tool to facilitate discussion among key stakeholders who don't usually meet was presented to course participants.

4. **Draft a plan of action for developing or refining the artesunate combination therapy policy tailored to the participants' home country**

At the end of the workshop, each country team presented a tentative action plan to develop or refine implementation of the artesunate combination therapy policy. Unfortunately, most malarial program managers were unable to attend the entire workshop, and so were largely unavailable to work with their technical staff to discuss relevant activities and sequencing of actions in the proposed action plans.

Two frameworks: the RPM Plus "Implemention Guide" and the Malaria Consortium, "Review of the Project Management Cycle: Supervision, Monitoring and Evaluation" were presented to the group on how to identify and prioritize gaps in ACT policy implementation as well as the associated monitoring and evaluation indicators. Participants were somewhat confused about which framework to use when developing or refining their plan of action. However, despite limited technical roles and with technical assistance provided by course facilitators, program staff was able to apply the implementation guide to identify and prioritize gaps in their current malaria drug policy.

Participant's Comments

According to the evaluation forms, the majority of the participants found the topics discussed very useful and important in helping them plan policy changes. Course feedback and recommendations for future courses are included in the participant's comments below:

> "Thank you for teaching us and so many things are completely good"

"The workshop is very important to share drug policy other country we hope to sustain"

"I am very happy for this workshop; the teacher very active and friendly"

"I hope after the course is finished every participants collaboration with other for supporting malaria program through ACTMalaria"

"Fruitful course for use; excellent session those who conducted the session; duration should be 3 weeks; operation plan should follow same guide line; nomination process should be emphasis according to country needs"

"The reading materials given are very relevant and useful for me; duration of workshop, topics include in the workshop is just right"

"It is not easy to organize the workshop like this. I am lucky to be going in this workshop; I am sure I will use the knowledge I got from here"

"Please use participatory methods more sin some areas to avoid boring"

"Everything is above average well done"

Collaborators and Partners

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Adjustments to Planned Activities and/or Additional Activities

During the second week of the work shop, each resource person was assigned the additional task of working one-on-one with country teams to ensure greater understanding and subsequent application of the implementation guide.

NEXT STEPS

Immediate Follow-up Activities

N/A

Program managers recommendations

The attending malaria program managers recommended standardizing treatment guidelines for countries with common borders as a possible theme for a future workshop. The same managers recommended supporting the attendance of more technical people to such courses.

RPM Plus recommendations

1. **Reschedule malaria program manager's participation**

As most malarial program managers were able to attend the workshop for a few days only, there were limited opportunities to work with their team of technical staff. It would be more valuable to reschedule malaria program managers participation at the end of the course so that technical staff and program manages can collaborate more effectively in developing and intervention action plan.

2. **Offer the course using the two track curriculum**

The original curriculum design and content of this course was modified to accommodate participants request for a shorter program. Consequently, the subject matter was presented to a combined group of progam managers and technical staff. RPM Plus recommends offering this course using the tow original learning tracts decided by ACTMalaria and partners to maximize opportunities for successful policy change. The syllabus for track one would target higher level decision makers, e.g. program managers and the course outline for track two would be directed at program technical staff. Near conclusion of the workshop, participants from both tracks would then come together and use the implementation guide to develop or refine interventions to implement policy change.

3. **Hold national level workshops to demonstrate how to apply the guide**

RPM Plus can provide technical assistance to national malarial program managers and staff in their respective countries to develop and implement an action plan. This alternative approach provides an opportunity for program managers and key stakeholders to participate in technical meetings so that a comprehensive action plan is developed and implemented.

4. **Application of the Implementation Guide**

The decision to change antimalarial policy and the subsequent implementation of the policy brings with it challenges and complexities at every level, involving a variety of stakeholders. The process requires participation of others beyond malaria program managers, ranging from departments with the MOH, to manufacturers and private providers. The guide can be used as a tool to facilitate discussion among key stakeholders who don't usually meet, as each step for rolling out a new treatment policy is appraised.

5. Include pharmaceutical management concepts in future ACTMalaria courses

While the guide's operational components incorporate the activities related to procurement and supply chain management, it is also important for malaria program managers and technical staff to be aware of the principles of pharmaceutical management for malarial. As a means of increasing this level of awareness, it is important to include pharmaceutical management concepts to improve access to, as well as the use of antimalarial medicines, in regional and national level courses offered through ACTMalaria. RPM Plus can provide technical assistance to review the availability and patterns of use of medicines for malaria treatment in public health and private facilities.

Agreement or Understandings with Counterparts

During the first week, ACTMalaria convened a closed meeting for the malaria program country directors attending the workshop. Those in attendance are listed in the box below.

Director	Country
Dr. Guo Xiaofang	PR China
Dr. Samlane Phompida	Lao PDR
Dr. Mustafa Kamal	Bangladesh
Dr. Ferdinand Laihad	Indonesia
Dr. Anuttarasakdi Ratchatatat	Thailand
Le Xuan Hung	Vietnam
Dr. Duong Socheat	Cambodia

The purpose of this meeting was to discuss the current status of each country's ACT policy and reach consensus on a number of issues. Each malarial program director agreed to the following:

1. Include artemisinin-based combination therapy as part of its AMDP
2. Treatment guidelines will include protocols for children and pregnant women
3. Treatment guidelines will include chemoprophylaxis for pregnant women and non-immune travelers
4. Include therapeutic efficacy surveillance
5. Conduct drug quality monitoring
6. Conduct quality assurance for diagnosis
7. Exchange information regarding adverse drug reactions

8. Information exchanged in this workshop will be made available on the ACTMalaria website. For non-member countries, permission will be required before downloading information.

Important Upcoming Activities or Benchmarks in Program

N/A

Annex 1. Contents and Objectives of the Workshop

NATIONAL INSTITUTE OF PARASITIC DISEASES
CHINESE CENTER FOR DISEASE CONTROL AND PREVENTION
&
JIANGSU INSTITUTE OF PARASITIC DISEASES
In collaboration with
ASIAN COLLABORATIVE TRAINING NETWORK FOR MALARIA (ACTMALARIA)

WORKSHOP ON ANTI-MALARIA DRUG POLICY IMPLEMENTATION REVIEW

Jiangsu Institute of Parasitic Diseases
Wuxi City, PR China
12 - 22 SEPTEMBER 2005

CONTENTS AND OBJECTIVES OF THE WORKSHOP

1. Background

ACTMalaria—the Asian Collaborative Training Network for Malaria was formed in 1996 primarily to address common malaria problems in the countries of the Mekong Region and Southeast Asia. Occupational migration which advances forest malaria transmission and the spread of multi-drug resistant *falciparum* are just two of the priority problems which the network hoped to address through joint human resource development and communication exchange. At present, the network includes 10 countries in the region, namely, Bangladesh, Cambodia, PR China, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Thailand and Vietnam.

Recognizing anti-malarial drug resistance as an important problem to tackle, the ACTMalaria Executive Board agreed to the development of a training course on Anti-Malarial Drug Policy Development. The course was conducted in 2000 and was co-hosted by National Malaria Control Programmes of Vietnam and China. The course took into consideration the issues related to the spread of drug resistance, patient non-compliance and consumer pressure, use of anti-malarial drugs by non-qualified practitioners, and the cost-effectiveness of introducing new but more expensive anti-malarial drugs. Since then, most of the ACTMalaria member countries have revised national anti-malarial drug policies and have introduced or considered the use of combination therapy. Much of these advancements were made possible through the Global Fund support.

The proposed workshop will review the most recent developments related to the countries drug policy implementation, discuss areas for improvement and potential for standardization of treatment guidelines especially along country borders.

2. Objectives

At the end of this workshop, the participants will have:

a) Assessed the implementation and effectiveness of current AMDP;

b) Used appropriate evidence to identify potential gaps and deficiencies in policy implementation and identify ways to improve its effectiveness;

c) Developed a plan of action for the implementation of the refinements to AMDP including M&E;

d) Applied problem-solving skills, consensus building among stakeholders and effective communications in advocacy for the AMDP.

3. Content

The workshop is divided into 7 sessions with topics grouped according to themes as follows:

Session No.	Theme	Duration
1	What is an Anti-malarial Drug Policy and how do I know if my country's AMDP is working effectively?	1 day and 1 hr
2	How do I know if my country's AMDP is working? (and presentation of country's current AMDP)	2 days
3	How do I obtain missing information	1 day
4	Do I have a broad-base support for the AMDP?	0.5 day
5	How do I implement the refinements in our country's AMDP?	1 day
6	How do I ensure that things are going well?	1 day
7	Presentation of Country Action Plans	0.5 day

All sessions will be moderated by facilitators (ACTMalaria alumni) from the MoH of Malaysia and Philippines. Participating technical resource persons and speakers for this workshop are from WHO/WPRO, United States Pharmacopoeia, Management Sciences for Health-USA, Malaria Consortium-UK, Research Institute for Tropical Medicine-DoH Philippines and the National Institute for Parasitic Diseases-China CDC.

4. Workshop Organization and Administration

Workshop is a collaborative effort between China CDC- National Institute for Parasitic Diseases in Shanghai City and Jiangsu Provincial Institute of Parasitic Diseases in Wuxi City and the ACTMalaria Secretariat (ACTMalaria Foundation, Inc.).

5. Participants

Participants proposed for this workshop should be currently (or in the near future) responsible for anti-malarial drug policy review/development, implementation, monitoring and evaluation

a. Group 1 – High level decision makers; High level Drug level Drug Regulatory Administrator (5 days)
b. Group 2 - Person responsible for anti-malarial drug policy review, development, implementation (12 days)

6. Operating Details

Venue and Accommodation: Provincial Institute of Parasitic Diseases
Workshop hours:

AM	0830 – 1145
PM	1330 – 1730
15 mins. Coffee/tea break between AM & PM sessions	
Lunch Break	1145 – 1330
Dinner	1730

Language: English Only
Dates: September 12-22, 2005
Funding Support: USAID through WHO/WPRO
Other Matters related to stay in Wuxi City: "Refer to Living Guidance for Foreigners in Wuxi" provided by the Hotel.

7. Daily Allowance and reimbursement of Airfares

Food and accommodation is provided free to all participants. Additional daily subsistence allowance of $15/day will be paid to participants by the course organizers with additional $55 to cover payment of terminal fees and airport transfer to and from official station or residence to the airport.

Reimbursements of airfares and visa application (if applicable) will be paid by ACTMalaria upon submission of receipts.

Annex 2. Antimalarial Drug Policy Development And Implementation, Part I

MSH Management Sciences for Health

Closing the gap between what is known about public health problems and what is done to solve them

AntiMalarial Drug Policy Development and Implementation
Part I

Marion Lynders
September 12-22 2005

MSH Management Sciences for Health

Pharmaceutical Management

Pharmaceutical management is the set of practices aimed at ensuring the timely availability and appropriate use of safe, effective, quality medicines and related products and services in any health care setting

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Session Objectives

1. Describe the pharmaceutical management cycle
2. Understand the importance of pharmaceutical management as an essential part of malaria control program

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The Pharmaceutical Management Cycle

Activities are divided into five main components:

1. Drug selection
2. Procurement
3. Distribution
4. Use
5. Management support

Pharmaceutical management involves many activities that must be carefully coordinated to ensure that the right drug, in the right quantities, of good quality, gets to the right patient when the patient needs it

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Why is Pharmaceutical Management Important?

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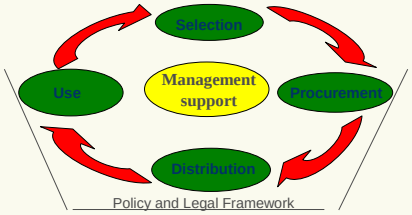
Pharmaceutical Management Supply System



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Components of Cycle

- These five components operate within a political, social, cultural, and economic context that influences the nature of the activities
- When the system is not functioning well, important drugs will not be used as they should be
- When the system is functioning well, the proper use of drugs will reinforce the proper selection, procurement and distribution of drugs

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Efficacy vs. Effectiveness (e.g., Drug X)

- Parasite clearance=80%
- Availability (Av)=90%
- Affordability (Aff) =100%
- Compliance/Adherence (Co) =100%

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Pharmaceutical Management Cycle and Malaria

- The Global Strategy for Malaria Control seeks to prevent mortality and reduce morbidity and social and economic losses from malaria
- One of the basic elements of the Global strategy is early diagnosis and prompt effective treatment
- To implement this strategy effectively, a well functioning pharmaceutical management cycle is imperative

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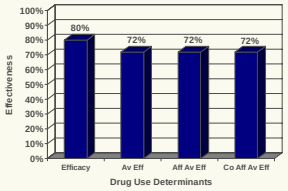
Efficacy vs. Effectiveness (e.g., Drug X)



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Efficacy vs. effectiveness

Program effectiveness:

- Drug efficacy
- Drug use determinants
  - ~ Availability
  - ~ Affordability
  - ~ Acceptability
  - ~ Adherence
    - ✓ Frequency and total number of doses
    - ✓ Adverse effects and acceptability
    - ✓ Ability of users to follow directions

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Efficacy vs. Effectiveness (e.g., Drug Y [ACT])

- Parasite clearance=99%
- Availability=50%
- Affordability=50%
- Compliance=50%

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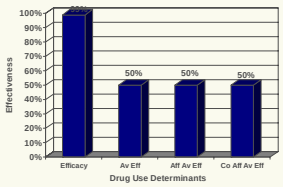
Efficacy vs. Effectiveness (e.g., Drug Y [ACT])



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Drug Management for Malaria: Selection

- Options for pregnant women (prevention and treatment)
  - ~ Issues of Malaria in pregnancy
    - ✓ Need to consider acceptability and compliance with antimalarials for prevention
    - ✓ Need to ensure availability of antimalarial for ANC use
    - ✓ Review data for safety in pregnant women, particularly for newer drug regimens e.g. ACT
    - ✓ Consider resistance to currently used IPT drug, SP
- Options for other specialized groups e.g. infants

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Drug Management for Malaria

MSH Management Sciences for Health

Drug Management for Malaria: Selection

- Decisions on which drugs will be available at each level of health care e.g., hospital dispensary, private sector shops
- Revision of Standard Treatment Guidelines and Essential Medicines Lists
  - – Change in malaria treatment guidelines must be
    - ✓ Harmonized with national drug formulary framework
    - ✓ Included into EML and formulary
    - ✓ Harmonized with other relevant guidelines e.g IMCI, RH

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Drug Management for Malaria: Selection

- Combination therapy is recommended by WHO, but
  - – 1st line- countries need to decide
  - – 2nd line-clear recommendations for use
  - – Severe malaria-quinine, IV use leads to higher costs
- Analysis of scientific evidence
  - – Patterns of drug resistance, treatment failure, mosquito species, morbidity and mortality data
  - – cost effectiveness, cost effective analysis
  - – health seeking behavior studies, community drug use surveys
- Review lessons learned from similar countries
- Analysis of barriers to implementing antimalarial policy

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Drug Management for Malaria: Selection

- Consider the capacity of health system to implement policy
- Financial burden for change
  - ~ Direct cost: ACT are more expensive, sustainability?
  - ~ Indirect cost: retraining of HW, new STGs, IEC/BCC etc.
- Commitment of the private sector (subsidies, social marketing, incentives)

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Drug Management for Malaria: Procurement

- Estimate drug needs (Quantification)
  - ~ Morbidity models
  - ~ Consumption models
- Procurement methods
  - ~ Competitive/noncompetitive
  - ~ Local/international
- Consider packaging options for combination therapies
- Consider different dosages of pre-packaged drugs for children-weight or age?

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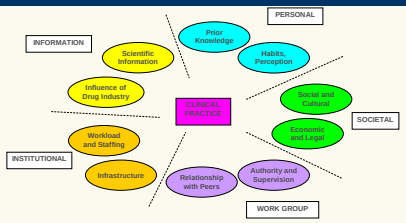
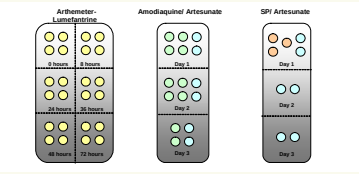
Factors Influencing Use of Antimalarials



MSH Management Sciences for Health

Drug Management for Malaria: Procurement Packaging: co-formulated vs pre-packaged



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Management Support Systems

- National Malaria Control Programs must liaise with many other ministerial departments, organizations, donors, etc.,
- Develop/refine STGs in collaboration with national formulary and EML
- Reduce availability of undesired product (e.g. phase out old drug)
- Manage finances

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Drug Management for Malaria: Distribution

- Distribution starts from customs clearance at the port to delivery to the end user
- Increased frequency of transportation and delivery of ACT to drug depots and health facilities
- High quality pharmaceutical management requires:
  - ~ Ideal storage areas (dry conditions, cold chain for RDTs)
  - ~ Adequate record keeping for good stock control
  - ~ Good system of monitoring, e.g., artemisinin derivatives have shorter shelf life
  - ~ Good system of recall for expired drugs

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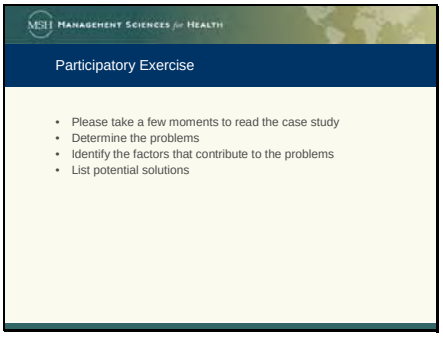
Management Support Systems

- Management Information Systems
  - ~ MIS must support implementation of ACT policy
  - ~ Should incorporate pharmacovigilance/ADR
- Monitoring and evaluation
  - ~ Appropriate indicators for malaria program
  - ~ Collaboration with other data collection activities e.g. DHSS to ensure collection of malaria specific indicators
- Human resources management
  - ~ Training of providers and HWs
  - ~ Monitoring and supervision essential


MSH Management Sciences for Health
Policy and Legal Framework
• Legal framework to support national malarial control policy implementation- case management and prevention
• Accreditation/licensing
~ Hospitals, clinics, pharmacies and providers
• Registration issues
~ Proof of safety, efficacy and quality
~ Pharmacopoeial standards
• Drug quality violations
~ Quality enforcement (inspections)
• Role of Drug Regulatory Authority
~ Regulation of undesirable antimalarials
~ Scheduling of antimalarials affects the level where they are available


MSH Management Sciences for Health
Participatory Exercise
• Please take a few moments to read the case study
• Determine the problems
• Identify the factors that contribute to the problems
• List potential solutions

Annex 3. Antimalarial Drug Policy Development And Implementation, Part II

Management Sciences for Health

Closing the gap between what is known about public health problems and what is done to solve them

AntiMalarial Drug Policy Development and Implementation Part II

Marion Lynders

September 12-22 2005

Management Sciences for Health

Assumptions

A situation analysis has been performed

- Selection of an effective first-line treatment for malaria consistent with the WHO recommendations has been made in consultation with all the RBM partners in the country
- Decision on dosage forms has been made
- Decision on diagnostic criteria has been made

Management Sciences for Health

Session Objectives:

1. Understand the actions that are needed to transition to and implement a national malaria treatment policy change to ACTs
2. Identify key indicators for effective monitoring and evaluation of appropriate drug management

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Framework for implementation of ACT policy (1)

The five elements of implementation are:

1. Financing and resource mobilization
2. Planning & coordination
3. Technical considerations
4. Operational considerations
5. Monitoring & Evaluation

Management Sciences for Health

Changing Malaria Treatment Policy to Artemisinin-Based Combinations: An Implementation Guide

The Implementation Guide and corresponding checklist was developed to provide guidance on **actions** needed to transition to and implement a national malarial treatment policy change to ACT

Management Sciences for Health

Financing and resource mobilization

- ACTs are 10 times more expensive than other antimalarials so there are multiple financial requirements to consider for the implementation process
- Developing a financing strategy
  - ~ National
  - ~ Donors (bilateral, GF)
- Consider cost-recovery structures
- Evaluate strategies for possible cost sharing
- Develop/review mechanisms to ensure financial accountability

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Planning and coordination

- Identify stakeholders
- Consider establishing working groups/task forces with assigned tasks such as:
  - Develop a schedule of Monitoring & Evaluation activities
  - Quantification of new medicines
  - Inventory management
- Determine each groups roles and responsibilities
- Define program indicators

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National treatment guidelines

- Determine which guidelines need to be revised
  - STG (National malaria treatment guidelines)
  - National formulary
  - Essential Medicines List
  - Integrated Management Childhood Illness/Reproductive Health guidelines
  - Health worker guides or handbooks
- Determine the process for revision, groups involved, TA needed and timelines
  - New guidelines *vs.* addendum
- Publish and disseminate new guidelines

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Technical considerations

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Public Health Messages

- Effective Behavior Change Communication and Information Education Communication messages
- Focused messages-households, health providers in public sector and in private formal and informal sectors
- Seek technical assistance and expertise from in-country partner's
- Develop a plan to implement these messages-printed materials, TV/radio spots, visual aids for health providers

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Drug regulatory considerations

- Registration of Artemisinin-based Combination Therapy
- Evaluate regulatory enforcement capacity and develop plan for strengthening
- Enhance prescribing and dispensing of ACTs
  - Include component in pre and in-service trainings
  - Case review and supervisory visits
  - Course of therapy packaging
  - Drug Utilization Review tool
  - Create patient demand
- Develop a plan to facilitate phasing out of old drugs and/or monotherapies if needed
- Review diagnostic criteria for treatment [clinical, biological (microscopic/RDTs)]

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Operational considerations

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Developing a phase-in plan

- Phased implementation
  - ~ Geographically
  - ~ Selection of some parts of health system i.e. public health services

Advantages:
- ~ Lower start up costs
- ~ Communication strategies can be tested and any problems corrected
- ~ Uptake of new policy can be monitored and modeled

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Quantification

Depending of phased or national level roll out:

- Obtain morbidity and/or adjusted consumption data from the field
- Determine pipelines and or drugs on order through central and peripheral data collection
- Calculate need- tools available, e.g. QUANTIMED
- Need to estimate requirement of RDTs?
- Adjust quantities based on budget

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Developing a phase-in plan

- Nationwide roll-out
  - Roll-out in entire country at same time

Advantages:
- ~ Prevents confusion as standardized messages delivered
- ~ Avoids political ramifications of selecting sites for first stages of implementation

Challenges:
- ~ Requires greater human resource capacity development
- ~ Requires greater financial outlay

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Procurement

1. GF funded procurement; need to adhere to GF policies
2. Develop procurement plan for non GF antimalarials and possibly biological testing equipment
3. Obtain technical assistance if needed-MSH/RPM Plus, other RBM partners
4. Develop tender documents
5. Harmonize national and grant procurement procedures
6. Synchronize actual procurement with financing
7. Monitor supplier performance

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Phase out old drug

- Determine quantities (pipeline) for old drug through central and peripheral data collection
- Adjust future procurements of current drugs to avoid accumulation of large pipelines of old drug when new drug is procured
- Develop plan for phase out of current drug from health system as new drug becomes available
- Withdraw old drug using plan developed above when change occurs

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Pre-packaging

- Determine product specifications. Is there a need to prepackage the product? If so, identify a supplier or manufacturer that can prepackage CT
- Develop weight/dosage schedules and appropriate pre-packaging for children
- Determine if same packaging should be used in public and private sectors

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Distribution and inventory management

- Develop/review distribution plan
- Review/develop inventory management systems to improve management of ACTs in peripheral health facilities
- Develop/review strategies to prevent leakage to private sector
- Develop/review distribution systems to remove expired stocks
- Develop/review systems to monitor efficiency of distribution system and re-distribution mechanisms
- Review storage areas and systems

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Monitoring & Evaluation

- Define performance targets
- Define program indicators (see sample M&E Indicators)
- Identify data needs *(including existing data)*
- Develop or adapt information systems (Drug Management Information Systems, store records, stock cards, etc.,)
- Identify and address human resources and information technology needs
- Determine who will be responsible for this activity
- Develop schedule for M&E activities
- Implement M&E plan

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Private sector

- Develop plan for making ACT available in private sector
- Consider appropriate interventions to enhance access
- Train relevant private sector providers

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Sample M&E Indicators: Treatment

Service Delivery Area	Output	Outcome
Prompt, effective anti-malarial treatment	1. Health facilities with no reported stock-outs of anti-malarial drugs	1. Children under 5 years of age with access to prompt, effective treatment 2. Patients with severe malaria receiving correct treatment

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Quality Assurance (QA) systems

1. Product efficacy-Drug resistance monitoring
   - ~ Sentinel surveillance sites
2. Product safety-Pharmacovigilance
   - ~ Develop/review system for monitoring of Adverse Drug Reactions
3. Product quality
   - ~ Develop/review systems for QA during procurement
   - ~ Develop/review systems for violations against drug quality standards
   - ~ Develop/review plan for post-marketing product quality surveillance

NEED MECHANISM FOR CO-ORDINATING QA DATA!!

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Thank you

There are no easy answers….

….but we still need to think about these complex issues and draw upon the knowledge, experience and expertise from colleagues at the district, provincial, national, regional and international levels. Timely review, update and implementation of antimalarial drug policy is an all encompassing process

Annex 4. Overview of Drug Issues

Overview of Drug Use Issues

Workshop Antimalaria Drug Policy Implementation Review
Marion Lynders, MSH/RPM Plus
September 2005

Rational Drug Use Surveys: Cambodia

- 2001 MSH/SEAM assessment indicated treatment of childhood ARI was problematic and no children received first line ATM therapy
- 2002 Baseline survey Community Malaria Drug Use practices in 4 provinces along Cambodian-Thai border (phase I)
- 2004 Follow up qualitative survey of priority malaria drug use problems (phase II)
- 2004 C-DMCI > Mission funding to learn about community drug management of childhood illnesses

Unit Objectives

- Define rational use
- Understand the factors affecting use of antimalarials
- Understand some common problems in use of antimalarials and what methods can be utilized to identify these problems
- Identify effective strategies to promote rational use of antimalarials

Understanding Malaria Drug Use Problems

Problem Identification (Phase I-2002)
- **What** is happening
- Understand problem **magnitude** and **priority**
- **Simple** enough tool for use by local staff, utilizing lay data collectors

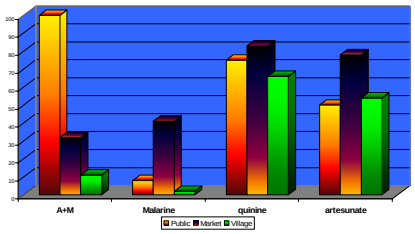
Problem Exploration (Phase II-2004)
- In-depth qualitative/quantitative data collection
- Experienced researchers
- **Why** and **how** things are happening

What is Rational Use of Drugs?

The rational use of drugs requires that patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and the community.

World Health Organization, 1988

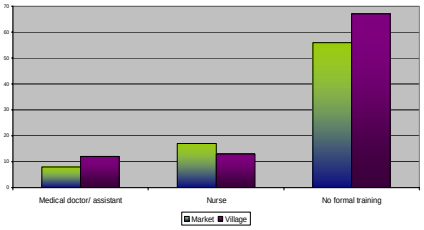
Drug Availability by Location



C-DMCI Survey areas: 2004

Province	Operational District
PhnomPenh	Choeung, Tbong
Siem Reap	Kralanh, Siem Reap
Pursat	Bakan, Sampov Meas
Kratie	Chhlong, Kratie
Koh Kong	Smach Meanchay, SreAmbel

Provider Training



Conditions Studied C-DMCI: 2004

- Malaria and severe malaria (fever and convulsions)
- ARI Pneumonia (fast breathing)
- ARI non-pneumonia (cough without fast breathing)
- Mild and bloody diarrhea

➢The symptoms were used not diagnosis

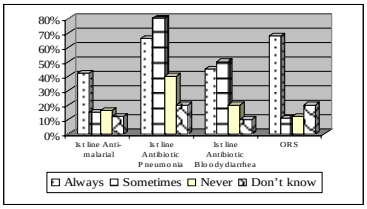
Malaria Drug Use Practices 2002: Select Findings

- 60% of market and village providers offered no blood tests
- 11% of patients received recommended prepackaged treatments
- Provider self-reported behavior was a poor predictor of actual practices
- No children received recommended treatment
- Village providers are an important source of treatment recommendations, but a poor one

Community Drug Management Childhood Illnesses 2004: Select findings

- 2574 fever cases ⇨9 received blood test prior to starting antimalaria treatment
- 5 of the 9 received antimalarial on 1st day
- 2 of the 9 received antimalarial on 2nd day

Availability of Medicines

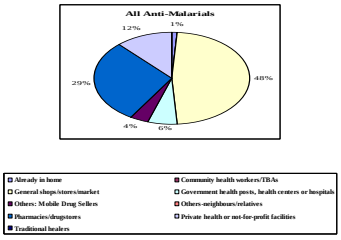


Availability of 1st line antimalarial

Type of Outlet

Health facility	n=269	57%
Licensed retailers	n=106	46%
Licensed individuals	n=111	41%
Unlicensed retailers	n=26	47%
Unlicensed individuals	n=867	10%

Source of Medicines



Knowledge of Appropriate Treatment of Malaria

Type of Outlet	Did Not Mention Key Symptoms	Mentioned Any Anti-Malarial	Mentioned 1st line Anti-Malarial
Health facility n=269	98%	84%	53%
Licensed retailers n=106	98%	55%	29%
Licensed individuals n=111	98%	69%	29%
Unlicensed retailers n=26	96%	23%	19%
Unlicensed individuals n=867	99%	24%	7%

Use of First Line Antimalarial

Response	1st Line Antimalarial			
	Fever		Convulsions	
	N	Percentage	N	Percentage
Yes	7	0.3	3	9
No	2566	99.7	30	91
Total	2574	100	33	100

Quality of /Packaging/Labeling/ Dispensing medicines

Type of Outlet	Included all items in label	Dispensed medicines outside of original packaging	Dispensed loose tablets in incorrect packaging	Mixed different pills in same container	Dispensed labeled medicines	Gave verbal instructions
Health facility n=269	43%	18%	18%	6%	19%	19%
Licensed retailers n=106	6%	38%	36%	26%	44%	36%
Licensed individuals n=111	4%	10%	10%	7%	14%	12%
Unlicensed retailers n=26	0	15%	15%	12%	23%	12%
Unlicensed individuals n=867	1%	3%	3%	3%	6%	3%

Identified Gaps (1)

Poor availability of essential medicines

- 1st line: A+M_2, Chloroquine
- Care givers cannot always get 1st line medicines where they live
- Private vendors most popular source of medicines

Diagnosis

- Most malaria treatment based on a clinical diagnosis rather than biological diagnosis
- Biological diagnosis requires availability of microscopes and skilled technicians
- Rapid diagnostic tests may be used for biological diagnosis (decision must be made during selection process)

Identified Gaps (2)

Poor knowledge of appropriate treatment

- 58% providers in survey have no medical background
- Lack of awareness of STGs/IMCI guidelines
  - Did not mention differentiating key symptoms
  - Unaware of 1st line therapy for malaria
  - 25% children received injection
  - Blood tests not conducted for fever symptoms before ATM therapy started
  - None of the children received first line therapy

Problems in Diagnosis

- Lack of microscopic capability (hardware as well as skill)
- Clinical diagnosis often leads to “overdiagnosis” as most fevers are treated as malaria
- Most malaria diagnosis occurs in the home or is done by an unqualified/untrained provider
- Most treatments are bought over the counter
- Rapid diagnostic tests are not widely used and are expensive

Understanding Drug Use

- Prescriber behaviors
- Dispensing behaviors
- Health systems characteristics
- Supply of pharmaceuticals and other commodities
- Patient and community behaviors

Prescribing

- Requires the prescriber to correctly diagnose the disease
- Requires the prescriber to have knowledge of the correct treatment as defined in the STGs
- Requires the prescriber to know the correct dosage to be given for the particular age group
- Requires the prescriber to adhere to the STGs for the drug and dosage

Problems in Prescribing

- The wrong antimalarials and or dosages are prescribed
  - ~ Lack of knowledge on current recommendation in STGs
  - ~ Lack of adherence to STGs (behavioral)
- Combination therapy:
  - ~ Only one component of combination is prescribed (due to provider non-adherence or patient pressure due to affordability)

Patient Use: Adherence

- Requires the patient to understand the instructions provided by the provider/dispenser
- Requires the antimalarials to be available in appropriate packaging with easy-to-understand instructions
- Requires the patient to take the antimalarial according to the prescribed dosage
- In the case of combinations, requires the patient to take both components
- Requires the patient to purchase and complete the entire course of therapy
- Dependent on the antimalarials being acceptable

Dispensing

- The antimalarial should be dispensed in appropriate packaging with clear instructions
- Dispensers should check patient's understanding of instructions for taking medicines by asking patient to repeat instructions
- The key concept is "right medicine in right quantity"
- May involve Directly Observed Therapy (e.g., S/P for IPT)

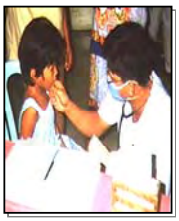
Patient Use: Non-adherence

- Non-adherence to prescribed treatment can be due to:
  - ~ Lack of understanding of instructions
  - ~ Stopping treatment due to feeling better
  - ~ Stopping treatment and giving antimalarial to family member
  - ~ Non-completion of the entire course due to affordability issues
  - ~ Taking one component of a combination
  - ~ Too many doses in one day (resulting in forgetting to take dose)
  - ~ Acceptability issues

Problems in Dispensing

- Incorrect interpretation of prescription (or diagnosis)
- Wrong drug is retrieved from stock
- Inaccurate counting or compounding
- Inadequate packaging or labeling
- Insufficient information and counseling to patient
- Dispenser may be pressured by the patient to dispense incomplete/single doses due to affordability issues

Identifying Problems with Medicine Use

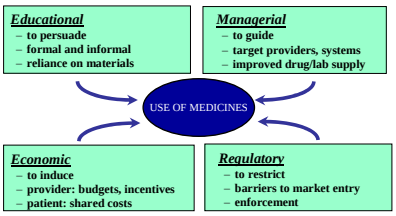


Selecting Appropriate Interventions to Improve Medicine Use

Managerial Methods for Structuring and Guiding Decisions

- Standard treatment guidelines
- Audit and feedback
  - Drug use evaluation
  - Peer group monitoring
- Clinical pharmacy programs
- Drug restrictions and control
- Supervision

Strategies to Improve Antimalarial Drug Use



Pre-packaging (1)

- Advantages
  - ~ Convenience, ease of use, safety, accuracy
  - ~ Ensures that patients get the right drugs at the right times and in the right dosages
  - ~ Improves patient compliance with recommended regimens
  - ~ Prevents medication dispensing errors
  - ~ Adds relatively little to total cost
  - ~ Encourages prescribers to agree on the most cost-effective average length of therapy
  - ~ Prevents overdosing or underdosing

Educational Methods

- Printed materials
  - Drug bulletins, newsletters, journals
  - Formulary manuals
  - Standard treatment guidelines
  - Job aids
- Face-to-face activities
  - Group: in-service education, training workshops, seminars
  - Individual: face-to-face (academic detailing)
  - Influencing opinion leaders
  - Patient education

Pre-packaging (2)

- Advantages:
  - ~ Increases the chance that patients will actually be given a full course
  - ~ Helps with dispensing
  - ~ Increases effective labelling, including the possibility of color-coded and symbolic labelling
  - ~ Facilitates social marketing
- Key strategy for non-fixed-dose ACTs

Annex 5. Case Study: Ensuring Rational Drug Use For Malaria

Rising resistance to chloroquine and other monotherapy drugs for managing malaria, particularly P. falciparum malaria, led the government to change the treatment policy to the use of combination therapy for case management of malaria. Recommended treatment guidelines were prepared to reflect this new policy. According to the guidelines, the recommended first-line treatment for uncomplicated P. falciparum malaria is a combination of artesunate and mefloquine. Second-line treatment for uncomplicated P. falciparum malaria is a combination of quinine and tetracycline. First-line treatment for malaria due to other malarial parasites continues to be chloroquine.

A few years after implementing this policy, government officials found that there was only a slight change in malaria morbidity and mortality patterns. This change was less significant than had been expected when the new treatment policy was instituted. A study was recommended to try to get a better understanding of what was actually happening. This study found that more than 80 percent of malaria patients in the country first seek care in the private sector, and more than 90 percent of antimalarials were purchased from private pharmacies and drug shops. The private sector was, therefore, the main source of treatment for malaria. There is currently little interaction between practitioners in the public and private health sectors, and little government oversight of the activities of private health facilities and providers.

The study also found that the diagnostic criteria for malaria used in private sector health facilities often differed from the national standard treatment guidelines (STGs), and also varied among facilities. Further, private sector facilities had limited laboratory diagnostic facilities. Most practitioners at these facilities were making the diagnosis of malaria on the basis of clinical symptoms alone. The ability to correctly diagnose malaria, therefore, varied significantly among the different cadres of providers in the private sector. The licensed prescribers, who had medical backgrounds, were more likely to make a correct diagnosis of malaria. Dispensers working in pharmacies and drug shops were more likely to have incorrectly diagnosed malaria when asked for a diagnosis by their customers. Most of these dispensers were not licensed to diagnose or to prescribe medicines. Laboratory diagnostic facilities were found to be equally limited in the public sector health facilities, although the providers in the public sector relied on the clinical diagnostic criteria outlined in the STGs to make their malaria diagnoses.

A review of the treatment received by patients found that, contrary to the guidelines, more than 80 percent of patients diagnosed with malaria were taking only artesunate monotherapy for their first-line treatment and more than 60 percent were taking only quinine monotherapy for their second-line treatment; only 10 percent of the patients had correctly completed the recommended combination therapy for malaria. This was true irrespective of whether they had sought treatment in public or private health facilities. In most cases, patients indicated that the medicines they were taking were what had been prescribed to them by the provider at the health facility at which they first sought treatment. However, in some cases, patients admitted that they had not filled the full prescription—because they could not afford to do so, the drugs prescribed were not available at the pharmacy, or they did not think it was necessary to take all the drugs. Duration of

treatment varied even among those who were receiving the same drugs. Patients who had first sought treatment at their local drug shop were less likely to have received any of the drugs recommended in the STGs, and in most cases were still using chloroquine.

Interviews with health-care providers working in private health facilities revealed that only about a quarter of them recommended the correct first-line treatment when presented with a hypothetical situation that required the use of first-line antimalarials. An equal proportion gave the correct second-line treatment when presented with a hypothetical situation that required the use of the second-line antimalarials. Providers working in public sector facilities were only slightly better at making the correct recommendations than were private sector providers. Slightly more than half of all providers had received any training on the use of antimalarials. Of those who had been trained, most were working in the public sector and had received training after the new STGs were issued. The private sector providers had received no training on the new STGs.

Based on this information, the government decided that its first intervention to improve the case management of malaria would be to provide the new treatment guidelines to private sector health providers. Other interventions would need to be designed to meet all the challenges identified in the study.

Case Study Questions:

1. What are the some of the drug use problems that may be occurring in the country?

2. Could you identify some of the factors that could be contributing to these problems? What component of the drug management cycle is related to each of these problems? What consequences do you foresee arising as a result of these factors?

3. Of the factors you identified, which are factors that, if adequately addressed, would have the greatest impact in addressing the problems with drug use?

4. Based on your analysis, do you agree with the decision of the government? Why or why not? What other steps should be taken to improve the use of the antimalarial drugs?

Annex 6. Facilitator's Guide Case Study Analysis: Ensuring Appropriate Use Of New Therapeutic Regimen For Malaria

1. What are the some of the drug use problems that may be occurring in the country?

- Provider noncompliance with STGs
- Nonadherence to prescribed treatment by patients
- Self-treatment by patients without consultation of health-care providers

2. Using the framework provided, identify some of the factors that could be contributing to these problems. What consequences do you foresee arising as a result of these factors?

Factors contributing to **provider noncompliance with STGs** include—

- Poor public health infrastructure—limited laboratory facilities
- Unlicensed prescribers and dispensers making treatment decisions
- Lack of awareness of the STGs
- Poor understanding of the STGs
- Limited or no access to training in the STGs, particularly among private sector providers
- Providers' preconceptions and habits—private sector providers, in particular, may not believe in the STGs or may not feel bound by the recommendations
- Limited regulatory oversight, particularly of the private sector

Factors contributing to **patient nonadherence to treatment** include—

- Patients' preconceptions about treatment—they may not believe or understand that it is necessary to take all the drugs prescribed
- Cost of treatment
- Availability of drugs prescribed at pharmacies

Factors contributing to the problem of **self-treatment by patients** include—

- Reliance on nonlicensed and nonqualified individuals for treatment advice
- Cost of treatment

Consequences that may arise from these factors include—

- Increased resistance of malarial parasites to the treatment drugs
- Increased morbidity and mortality due to malaria

3. Of the factors you identified, which factors, if adequately addressed, would have the greatest impact in addressing the problems with drug use?

- Factors associated with provider noncompliance with STGs—particularly the lack of regulatory oversight of the private sector activities
- Factors associated with patient nonadherence to treatment

4. Based on your analysis, do you agree with the decision of the government? Why or why not? What other steps should be taken to improve the use of the antimalarial drugs?

The government's decision is an appropriate first step. However, simply providing the guidelines to the private sector is not sufficient, as it does not ensure that private sector providers will read, understand, and use the guidelines.

Other interventions could include managerial, educational, and regulatory changes.

Managerial interventions could include—

- Reinforcement/strengthening of the public health infrastructure—improve drug and commodity supply; improve lab facilities and access to these facilities
- Strengthening of supervisory systems—develop systems for enhancing private sector activities

Educational interventions could include—

- Development and implementation of regular training programs for all providers on antimalarials and STGs for malaria
- Development of materials to be used for educational and informational activities—target patients; public and private providers at health facilities and local drug stores

Regulatory interventions could include—

- Development and enforcement of guidelines to ensure availability and quality of

antimalarial

- Review of licensing requirements and enforcement of regulations stipulating who can prescribe or dispense antimalarials
- Development of regulatory systems to monitor and support private sector activities

Annex 7. Implementation Guide and Checklist

Abstract

The decision to change the antimalarial treatment policy and the subsequent implementation of the policy brings with it challenges and complexities at every level, involving a variety of stakeholders, ranging from departments within the Ministry of Health (MOH) to manufacturers and private providers.

While there are some guidelines and documents on the elements that need to be considered when changing first-line treatment including the levels of drug resistance considered acceptable before countries should begin the process of review, there is no guidance on the steps required when rolling out a new treatment policy for national-level implementation. It must be noted that the formulation, implementation, and monitoring of policies and the appraisal of new options should be a continual process, because of growing parasite resistance to new therapies.

The purpose of the ACT Implementation Guide[1] is to provide guidance to countries on the actions that need to be taken to implement national policy changes for the first-line treatment for malaria to an ACT consistent with WHO's policy recommendations. It addresses operational and technical considerations for both the public and private sectors, and it may be used as a planning tool to identify technical assistance and resource needs.

For further information on the ACT Implementation Guide, please contact Marion Lynders at mlynders@msh.org.

[1] Rational Pharmaceutical Management Plus Program. 2005. *Changing Malaria Treatment Policy to Artemisinin-Based Combinations: An Implementation Guide.* Submitted to the U.S. Agency for International Development by the RPM Plus Program. Arlington, VA: Management Sciences for Health.

http://rbm.who.int/rbm/Attachment/20050418/malariaTreatmentPolicyMarch2005.pdf

ANNEX 8. List of Participants

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